



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

B

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,261	12/02/2003	Hua Wang	22727/04148	5627

24024 7590 10/11/2006

CALFEE HALTER & GRISWOLD, LLP  
800 SUPERIOR AVENUE  
SUITE 1400  
CLEVELAND, OH 44114

EXAMINER

CHO, DAN SUNG C

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/727,261

Applicant(s)

WANG ET AL.

Examiner

Dan-Sung C. Cho

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

*Claims 1-30 are pending.*

### ***Election/Restrictions***

1) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 9-12, 21-24, drawn to a method of detecting Alicyclobacillus and Geobacillus through 16S detection, classified in class 435, subclass 6
- II. Claims 5-8, drawn to a method of drawn to a method of detecting Alicyclobacillus and Geobacillus through Shc detection, classified in class 435, subclass 6.
- III. Claims 13-16, 17-20, drawn to a method of detecting mold and yeast through 16S detection, classified in class 435, subclass 6
- IV. Claim 25, drawn to a kit for detecting fungi through 16S detection, classified in class 435, subclass 24.32
- V. Claim 26, 28, 29, 30, drawn to a kit for detecting Alicyclobacillus and Geobacillus through 16S, classified in class 435, subclass 24.32
- VI. Claim 27, drawn to a kit for detecting Alicyclobacillus and Geobacillus through Shc, classified in class 435, subclass 24.32

2) The inventions are distinct, each from the other because of the following reasons:

Groups of I, II and III are distinct and unrelated from each other because I is drawn to detection of Alicyclobacillus and Geobacillus through 16S detection; II, Alicyclobacillus and Geobacillus detection through Shc detection; and III, mold and

Art Unit: 1634

yeast detection through 16S detection. Each group is drawn to inventions of detecting different microbes or genes and encompasses distinct inventions. A search of Alicyclobacillus and Geobacillus through 16S, for example, will not be coextensive with the search for Alicyclobacillus and Geobacillus Shc or mold/yeast 16S.

3) Groups IV, V and VI are distinct and unrelated from each other because IV is drawn to different kits of detecting Alicyclobacillus and Geobacillus through 16S detection (V), detecting of fungi through 16S detection (IV) and detecting of Alicyclobacillus and Geobacillus through Shc detection (VI). Each group is drawn to inventions of detection methods for different microbes and encompasses distinct inventions. A search of Alicyclobacillus and Geobacillus 16S, for example, will not be coextensive with the search for mold/yeast 16S.

4) Groups I and V; II and VI; and III and IV are related as product and process of use. Groups I~III are drawn to methods of microbial detection through the detection of 16S or Shc, Groups IV~VI to a kit that can be used to detect specific microorganism. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in materially different methods including purification, isolation, hybridization, aptamer, antisense methods, for example.

Art Unit: 1634

- 5) Groups I and VI or IV; II and V or IV; III and V or VI are distinct and unrelated from each other because each combination is not disclosed as capable of being used together. For example, I is drawn to a detection method of Alicyclobacillus and Geobacillus through 16S detection while IV is drawn to a kit of detecting fungi through 16S detection and VI, to Alicyclobacillus and Geobacillus through Shc detection. II is drawn to a detection method of Alicyclobacillus and Geobacillus through Shc detection while V is drawn to a kit of detecting Alicyclobacillus and Geobacillus through 16S detection and IV, to fungi through 16S detection. III is drawn to a detection method of mold and yeast through 16S detection while V is drawn to a kit of detecting Alicyclobacillus and Geobacillus through 16S detection and IV, to fungi through 16S detection. A search of Alicyclobacillus and Geobacillus 16S, for example, will not be coextensive with the search for mold/yeast 16S.

**Restriction Requirement Applicable to All Groups:**

- 6) Claims 1, 5, 9, 13, 17, 24, 25 contain sequences that are patentably distinct from each other because they are distinct and unrelated sequences, i.e. these sequences are unrelated because they have distinct nucleotide sequences and the protein encoded by one sequence differs in structure from the protein encoded by another segment. A restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

Art Unit: 1634

- 7) Claims 1, 5, 9, 13, 17, 24, 25 contains 4 individual, independent and distinct nucleotide sequences, namely, 16S, 1327-1460; 16S, 8752-813; 16S, 50-613; and Shc, 334-485. These sequences differ from each other in sequences, length, gene identification and/or region of a gene. Accordingly, these claims are subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (November 19, 1996).
- 8) Applicant is required to select one of the individual sequences for examination. The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers). For Group III, invention are drawn to primers that amplify two different regions of 16S. The applicant is required to select one region and its corresponding pairs of primers.
- 9) Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

#### **Notice of Possible Rejoinder**

- 10) The examiner has required restriction between product and process claims, namely Groups I and V; II and VI; and III and IV. Where applicant elects claims directed to


Art Unit: 1634

the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

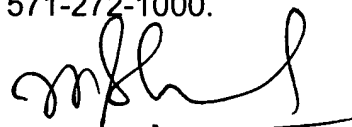
- 11) In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

**Conclusion**

- 12) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dan-Sung C. Cho whose telephone number is 571-272-9933. The examiner can normally be reached on Mon - Fri, 8-5 EST.
- 13) If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 14) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Dan-Sung C. Cho  
Examiner  
AU1634



RAM R. SHUKLA, PH.D.  
SUPERVISORY PATENT EXAMINER